K113165 P1/3

FEB - 2 2012

## Section 5 – Summary of Safety and Effectiveness

### 510(k) Summary of Safety and Effectiveness

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|---|---|
| Submission Date: | October 21, 2011 |
| 510(k) Submitter/Holder: | Athena GTX<br>3620 SW 61st Street, Suite 395<br>Des Moines, Iowa 50321<br>Ph: 515.288.3360 Fax: 515.288.3394 |
| Company Contact: | Sean Mahoney (Chief Technical Officer)<br>Office Phone Number: 515.288.3360<br>Email: smahoney@athenagtx.com |
| Trade Name: | mini-Medic™ |
| Common Name: | Patient Physiological Monitor |
| Classification Name: | Patient Physiological Monitor (Refer to 21 CFR 870.2300)<br>Cardiac Monitor (Including cardio tachometer and rate alarm) (Refer to 21 CFR 870.2300)<br>Clinical Electronic Thermometer (Refer to 21 CFR 880.2910)<br>Oximeter (Refer to 21 CFR 870.2700)<br>Radiofrequency Physiological Signal Transmitter and Receiver (Refer to 21 CFR 870.2910) |
| Classification Regulation: | Class II |
| Basis for Submission: | New device design |
| Legally Marketed (Predicate) Devices: | Athena GTX Wireless Vital Signs Monitor (WVSM) K101674<br><br>Envitec-Wismar GmbH OxiPen Pulse Oximeter K070193<br><br>Exergen Temporal Scanner Thermometer K011291<br><br>Nihon Kohden BSM-2300 Series Bedside Monitors K011918<br><br>Nonin 8000R Reflectance Sensor (specified accessory in Nonin 2500A monitor) K050056 |

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Device Description:

The Athena GTX mini-Medic™ wireless vital signs monitor system is a small, lightweight, rugged, and highly portable patient monitor designed to measure $SpO_2$, cardiotachometer, skin temperature and pulse wave transit time (PWTT). Vital signs are displayed directly on the forehead sensor and transmitted wirelessly to a handheld display unit. Reports and data file saving is done via wireless download to a PC.

Predicate Device Overview:

The mini-Medic™ is designed for the same application and intended use as the combination of listed predicate devices. The mini-Medic™ is capable of the same heart rate, functional oxygen saturation, pulse rate, pulse wave transit time and IR temperature measurements as have been provided by the combination of predicate devices referenced above.

Intended Use:

The mini-Medic™ system is comprised of a minimum of one Forehead Sensor Unit and one Handheld Display Unit, and is intended for use on patients who are eighteen (18) years and over.

The mini-Medic™ system is indicated as a single or multi-parameter vital signs monitor for $SpO_2$ and pulse rate via an integrated $SpO_2$ forehead sensor, and/or heart rate from ECG electrodes, and forehead skin surface temperature from an infrared temperature sensor. Pulse wave transit time (PWTT) is obtained utilizing pulse measurements from the integrated $SpO_2$ forehead sensor and ECG electrodes placed on the upper chest. Pulse wave transit time (PWTT) is used to track changes in blood pressure. Skin temperature is used as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature for hyperthermia and hypothermia conditions.

Patient data may be entered on the Handheld Display Unit. The mini-Medic™ system provides vital parameter alarms and a patient composite/summary alarm.

Patient information and system commands are transmitted using wireless radio communications between the Forehead Sensor Unit and the Handheld Display Unit. Stored patient

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data may be output, printed, downloaded and saved via a dedicated mini-Medic™ PC Software application.

Typical locations for the use of the mini-Medic™ system are: pre-hospital (i.e., at the point of injury or trauma scene), hospital, healthcare facility, emergency medical application, and during ground or air transport. The monitor is intended to be used by trained healthcare providers in military and civilian roles including doctors, nurses, combat medics, combat lifesavers, EMT's, and paramedics.

Summary of Testing:

Testing on the mini-Medic™ has been completed to verify compliance with recognized national and international standards for safety and performance for medical devices, and particular requirements applicable to this device.

Conclusion:

Based on the results for all safety and compliance testing performed, it is the opinion of Athena GTX the mini-Medic™ wireless vital signs monitor system is safe and effective, and is substantially equivalent to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 2 2012

Athena GTX
c/o Mr. Sean Mahoney
Chief Technical Officer
3620 SW 61st Street, Suite 395
Des Moines, Iowa 50321

Re: K113165
Trade/Device Name: mini-Medic™ Wireless Vital Signs Monitor System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Codes: MWI, DQA, FLL, DRT. DRG
Dated: January 10, 2012
Received: January 11, 2012

Dear Mr. Mahoney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Section 4 - Indications for Use Statement

### Indications for Use Statement

510(k) Number: K113165

Device Name: mini-Medic™ System

Indications for Use:

The mini-Medic™ system is comprised of a minimum of one Forehead Sensor Unit and one Handheld Display Unit, and is intended for use on patients who are eighteen (18) years and over.

The mini-Medic™ system is indicated as a single or multi-parameter vital signs monitor for SpO2 and pulse rate via an integrated SpO2 forehead sensor, and/or heart rate from ECG electrodes, and forehead skin surface temperature from an infrared temperature sensor. Pulse wave transit time (PWTT) is obtained utilizing pulse measurements from the integrated SpO2 forehead sensor and ECG electrodes placed on the upper chest. Pulse wave transit time (PWTT) is used to track changes in blood pressure. Skin temperature is used as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature for hyperthermia and hypothermia conditions.

Patient data may be entered on the Handheld Display Unit. The mini-Medic™ system provides vital parameter alarms and a patient composite/summary alarm.

Patient information and system commands are transmitted using wireless radio communications between the Forehead Sensor Unit and the Handheld Display Unit. Stored patient data may be output, printed, downloaded and saved via a dedicated mini-Medic™ PC Software application.

Typical locations for the use of the mini-Medic™ system are: pre-hospital (i.e., at the point of injury or trauma scene), hospital, healthcare facility, emergency medical application, and during ground or air transport. The monitor is intended to be used by trained healthcare providers in military and civilian roles including doctors, nurses, combat medics, combat lifesavers, EMT's, and paramedics.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device ~~Evaluation~~ (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113165